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REMARKS

Claims 1-7, 10-34 and 36-41 are pending in the present application. The time period to file a response in this case without an extension of time was January 22, 2004. Applicant has petitioned for a one-month extension and has timely filed this response on February 23, 2004. Applicant has amended the specification to include reference numeral 20. The drawings are now in compliance with 37 C.F.R. 1.84(p)(5) and in condition for allowance. Applicant has also amended the specification to correct any informalities and to provide proper antecedent basis for the claimed subject matter.

Applicant gratefully acknowledges that claims 25-34 are allowed and that claim 5 would be allowed if rewritten in independent form. Applicant has rewritten claim 5 in independent form as new claim 41 and this claim is now believed to be allowable. Regarding the remaining rejected claims, claims 1-7 and 34, reconsideration is respectfully requested.

The Examiner rejected claims 1-3 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,628,724 to DeBusk et al. The Examiner has taken the position that, "DeBusk et al. disclose a wound dressing and a delivery system comprising a polymeric film (layers 20 and 24), a first adhesive (22) coated on a first side of the polymeric film, a handle (tab 26) adhered by adhesive (28) to a second non-adhesive side of the polymeric film and a release liner (cover 42) covering the adhesive coated surface and extending beyond at least a first edge of the polymeric film." Notably, the Examiner has stated as follows:

[t]he Applicant should note that the first adhesive on the first side of the polymeric film adheres more aggressively to the skin than a pressure sensitive adhesive adheres to the polymeric film in that the handle can be removed from the polymeric film once the polymeric film is adhered to the skin of a patient (Figs. 5-7).

The DeBusk et al. patent does not teach or suggest a handle adhered to a second non-adhesive side of the polymeric film, but instead teaches a paper tab 26 adhered with an adhesive 28 to a carrier sheet 24. Further, the DeBusk et al. patent does not teach or suggest the requirement that the first adhesive (22 in the case of the DeBusk et al. patent) adhere more aggressively to the skin than the pressure sensitive adhesive (28 of DeBusk et al.) to allow the

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handle to be removed from the polymeric film once the polymeric film is adhered to a patient's skin.

To the contrary, the DeBusk et al. patent teaches that using the tab 26 as a handle, the carrier sheet 24 is lifted from the film dressing, "leaving the dressing 20 adhered to the wound site in a smooth unwrinkled disposition." (Column 5, lines 41-42). To anticipate a claim, the reference must teach every element of the claim. MPEP §2131. The DeBusk et al. patent does not teach a handle adhered to a second non-adhesive side of the polymeric film and does not teach the requirement for the first adhesive adhering more aggressively to the skin than the pressure sensitive adhesive to allow the handle to be removed from the polymeric film once the polymeric film is adhered to a patient's skin. Accordingly, claim 1 is in condition for allowance.

Claims 2 and 3 have also been rejected under 35 U.S.C. §102(b) as being anticipated by the DeBusk et al. patent. Claims 2 and 3 depend from independent claim 1. The DeBusk et al. patent does not teach or disclose the above-noted novel features of independent claim 1 in combination with the use of a polyurethane film (claim 2) or the use of a silicone coated release liner (claim 3). Accordingly, because independent claim 1 is believed to be in condition for allowance and because the DeBusk et al. reference does not disclose the novel features of dependent claims 2 and 3 as discussed above, dependent claims 2 and 3 are believed to be in condition for allowance.

The Examiner rejected claims 34 and 35 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,520,629 to Heinecke et al. Applicant has amended claim 34 to include, "wherein said U-shaped handle includes a handling tab projecting from said base thereof, away from said polymeric film." To anticipate a claim, the references must teach every element of the claim. MPEP §2131. The Heinecke reference does not disclose the novel features of claim 34. The Heinecke et al. reference does not disclose a handling tab projecting from the handle base and away from the polymeric film. Rather, the Heinecke et al. reference discloses that,

[i]n use, carrier window portion 42 is first removed from wound treatment composite 30, simultaneously removing adhesive strips

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46 from the composite. After removal from wound treatment composite 30, adhesive strips 46 extend beyond carrier window portion 42, and are readily available for grasping by the user and applying adhesive strips 46 to the skin of a patient or any other desired substrate.

The Heinecke patent further states, "[I]ner 36 is then removed from adhesive coated backing 32 by the user, and wound treatment composite 30 is then located over the site to be protected." (Column 4, lines 22-33).

In contrast, Applicant's present invention is applied by folding back release liner 35 in the vicinity of tab 31a, grasping tab 31a and peeling the assembly of handle 31 and polymeric film 33 away from release liner 35. The applicator then applies the polymeric film 33 to the patient's skin, and peels handle 31 away from the applied polymeric film 33. Therefore, the prior art of record does not teach or disclose the above noted novel features of amended claim 34. Accordingly, claim 34 is in condition for allowance.

Claim 4 has been rejected under 35 U.S.C. §103(a) as being unpatentable over DeBusk et al. in view of U.S. Patent No. 4,753,232 to Ward. In order to establish a prima facie case of obviousness, three basic criteria must be met, according to the Manual of Patent Examining Procedure, §706.02(j). These three are repeated as follows. Firstly, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Secondly, there must be a reasonable expectation of success. Thirdly, the prior art reference (or references) must teach or suggest all the claim limitations. Applicant submits that the applied references do not established a prima facie case of obviousness for rejecting claim 4.

In regard to the first criterion of obviousness, there is no suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The Examiner has stated,

DeBusk et al. failed to teach the adhesive as placed on the undersurface of the handle (tab 26). However, Ward discloses an adhesive wound dressing and various delivery systems therefore. The delivery systems of Ward include non-adhesive handles (Fig. 10), handles having adhesive over the entire undersurface (Fig. 2) and handles partially coated with adhesives (Fig. 5), depending upon the delivery method.

Claim 4 is dependent upon independent claim 1, claim 1 requires, "a handle adhered to a second non-adhesive side of the polymeric film . . ." and requires the first adhesive adhere more aggressively to the skin than the pressure sensitive adhesive to allow the handle to be removed from the polymeric film once the polymeric film is applied to a patient's skin. In this regard, Applicant's present invention teaches away from that which is disclosed in DeBusk et al. in view of Ward. The DeBusk et al. patent does not teach or suggest a handle adhered to a second non-adhesive side of the polymeric film, but instead teaches a paper tab 26 adhered with an adhesive 28 to a carrier sheet 24. Accordingly, there is no suggestion or motivation in either the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings.

In regard to the second criterion of obviousness, there is no reasonable expectation the combination would be successful. For example, if one were to combine the DeBusk et al. reference with the Ward et al. reference one would not achieve the success as claimed in Applicant's invention, let alone claim 4. Claim 4 requires, among other things, a handle adhered to a second non-adhesive side of the polymeric film with a pressure sensitive adhesive, wherein the handle has an undersurface that is entirely coated with a pressure sensitive adhesive, with a portion of said handle projecting beyond said first edge of said polymeric film and overlying said release liner. Further, claim 4 requires that the first adhesive adhere more aggressively to the skin than the pressure sensitive adhesive to allow the handle to be removed from the polymeric film once the polymeric film is adhered to a patient's skin. Accordingly, there is no reasonable expectation that the combination would be successful.

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In regard to the third criterion of obviousness, the prior art reference does not teach or suggest all of the claim limitations. Even if it would have been obvious to combine the DeBusk et al. reference with the Ward et al. reference, the resulting combination would not have taught, suggested, or led to the expectation that is embodied by claim 4. Accordingly, claim 4 is in condition for allowance.

Claims 6-9 are rejected under 35 U.S.C. §103(a) as being unpatentable over DeBusk et al. in view of Heinecke et al. There is no suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The Examiner has stated, "DeBusk et al. failed to disclose a U-shaped handle. However, Heinecke et al. disclosed an adhesive dressing and a delivery system therefore, wherein the delivery system comprises a U-shaped handle (44), see Fig. 3 as an alternate means for delivering the adhesive dressing." The Examiner has also stated, "[i]n view of Heinecke et al., it would have been obvious to one of ordinary skill in the art to modify the shape of the handle of DeBusk et al. to include a U-shaped handle as an alternate means for delivering the adhesive dressing."

Applicant's present invention teaches away from the combination of DeBusk et al. in view of Heinecke et al. In Applicant's present invention, claim 6 depends from independent claim 1. Claim 6 requires a handle adhered to a second non-adhesive side of the polymeric film and requires the first adhesive adhering more aggressively to the skin than the pressure sensitive adhesive to allow the handle to be removed from the polymeric film once the polymeric film is adhered to a patient's skin. Claim 6 further requires that the handle is U-shaped having a pair of spaced legs secured along two edges of the film and a base joining the leg secured along and extending beyond a third edge of the polymeric film. Claim 7 depends from claim 6 and requires that the U-shaped handle include a handling tab. Accordingly, there is no suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings.

Further, the prior art reference does not teach or suggest all of the claim limitations. Even if it would have been obvious to modify the shape of the handle of the DeBusk et al. patent to include a U-shaped handle as an alternate means for delivering the adhesive dressing,

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the resulting combination would not have resulted in a handle adhered to a second non-adhesive side of the polymeric film with a pressure sensitive adhesive or resulted in the requirement that the first adhesive adhere more aggressively to the skin than the pressure sensitive adhesive to allow the handle to be removed from the polymeric film once the polymeric film is adhered to a patient's skin. Accordingly, claims 6 and 7 are in condition for allowance.

Accordingly, Applicant respectfully submits that all of the pending claims are novel and not obvious in view of the references cited by the Examiner and are in condition for allowance. A notice to that effect is earnestly solicited.

Applicant has made an earnest effort to the place the present application in condition for allowance. In the event there are any remaining informalities or any other issues requiring Applicant's assistance, Applicant requests that the Examiner call the undersigned attorney at (616) 949-9610.

Respectfully submitted,

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